

REMARKS

Claims 19-41 are pending in the application. Claims 24, 35 and 39-41 are cancelled by this amendment. Claims 19-23, 25-34, 36-38 have been amended to further define technical features of the present invention. Support for the amended claims is found in the Specification, at, for example, the section entitled "Objects of the Invention." No new matter has been added.

No additional fee is believed necessary for entry and consideration of this Amendment.

The following remarks are believed to be fully responsive to the Final Office Action mailed January 5, 2005 as well as the Advisory Action which was mailed on June 2, 2005 in response to Applicants' Amendment After Final Rejection filed on May 5, 2005. Unless specifically noted, the rejections and objections addressed refer to those of the Final Office Action. Favorable reconsideration is requested.

I. "Written Description" Objection to Claims 39-41

Claims 39-41 stand rejected under the first paragraph of 35 U.S.C. 112 as allegedly failing to comply with the written description requirement.

Although Applicants disagree with the examiner's rejection, because co-reactants were described in the PCT published application U.S. 89/04859 which was incorporated by reference and were clearly understood by a skilled artisan at the time that the specification was filed, in order to expedite prosecution, claims 39-41 have been cancelled. The rejection is thus rendered moot.

II. "Written Description" Objection to Claims 19-41**A. "Substance"**

Applicants submit that claims 19-41 fully comply with the written description requirement. A skilled artisan would readily recognize what meaning the term “substance” encompasses and that Applicants were in possession of the claimed invention.

Nonetheless, in an effort to expedite prosecution, claim 19 has been amended to recite a “composition,” a regular term of art in patent law. Moreover, the term composition is literally described in the specification (*in haec verba*). “It is also an object of this invention to provide compositions and assays using graphitic nanotubes (fibrils) which can be labeled with compounds capable of being induced to luminesce.” *Specification* at section entitled “Objects of the Invention.”

In this connection the Examiner’s attention is directed to MPEP §§ 2163.02. As noted therein, the proper standard for determining whether an applicant has satisfied the “written description” requirement of the first paragraph of 35 USC § 112 is whether the applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date of the application, the applicant was in possession of the invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

Applicants respectfully submit the original specification adequately described the claimed invention pursuant to the first paragraph of 35 USC 112, because one of ordinary skill in the art would readily understand that Applicants had possession of the claimed composition. MPEP 2163.02. Indeed, an examiner has the initial burden of presenting, by a preponderance of evidence, why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. MPEP 2163.04, citing *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97.

Further, claim 19, as amended, is explicitly directed to enzyme co-factors selected from a group consisting of NADH, NADPH, NAD⁺, NADP⁺ or a derivative thereof. Accordingly, Applicants submit that the original specification adequately describes the claimed invention under the first paragraph of 35 USC 112.

B. Configuration of Claimed Components

In the Advisory Action, the Examiner maintained the rejection of the claims under 35 USC 112, second paragraph, alleging that the configuration of claimed components is unclear.

In response Applicants note that the present claims *do* include the configuration where the ECL label is covalently attached directly to the enzyme co-factor. Such configurations have diagnostic utility and are explicitly described in the Specification. These embodiments are recognized by the Examiner, thus supporting Applicants' assertions that the claims are not deficient under 35 USC 112.

III. "Enablement" Rejection

Claims 19-38 are rejected under 35 U.S.C. 112, first paragraph. The Examiner alleges that certain configurations of reactive components on the nanotube are required for the composition to be useful for the stated purpose of the invention." (Final Office Action, page 3).

Applicants respectfully traverse.

There is no reasonable basis to assert that the claims be limited to "specific distances and types of attachments" as suggested in the Office Action dated June 17, 2004 at page 2. The fact that the claim may encompass some non working embodiments is not dispositive. Specification provides extensive disclosure of the claimed compositions and various methods used to prepare the claimed compositions. The chemical compositions in the preferred embodiments of the

instant invention were actually reduced to practice as indicated by Examples 10 and 11 and production of the other compositions of the currently pending claims is fully within a purview of a skilled artisan. Every stage of the process is disclosed in a great detail therefore enabling a person of ordinary skill in the art to practice the claimed invention without undue experimentation.

Applicants submit that one of ordinary skill in the art would be able to practice the presently claimed subject matter in view of the specification and the prior art without undue experimentation. The test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976). *See also*, MPEP § 2164.01. The fact that experimentation may be complex does not necessarily make it undue if those skilled in the art typically engage in such experimentation. *In re Certain Limited - Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm'n 1983); *M.I.T. v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985); *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988); MPEP § 2164.01.

Contrary to the Examiner's suggestion, the specification need not provide examples or specific description of embodiments for the entire scope of the invention. Detailed procedures for making and using an invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. MPEP §2164. A patent does not teach, **and preferably omits**, that which is well known in the art. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984); MPEP § 2164.01. Even assuming *arguendo* that some compositions are non-functional for the stated

purpose, it is not necessary for this approach to be successful in every case to satisfy the enablement requirement of 35 USC 112, first paragraph.

Applicants submit that one of ordinary skill in the art would be able to practice the claimed invention without undue experimentation in view of the teachings set forth in the specification.

IV. Definiteness Rejection

Claims 19-38 stand rejected under 35 USC 112, second paragraph, as allegedly being indefinite.

Applicants submit that the terms in the claims are sufficiently clear and definitely to one of ordinary skill in the art in compliance with 35 USC 112, second paragraph.

(a) With respect to the term “substance”, claim 19 has been amended to recite “composition”, as noted above. The basis of the rejection is thus moot.

With respect to the term “ECL co-reactant”, claim 19 as amended is explicitly directed to enzyme co-factors selected from a group consisting of NADH, NADPH, NAD⁺, NADP⁺ or a derivative thereof.

Applicants thus urge that the claims are sufficiently clear and definite to one of ordinary skill in the art when properly construed in view of the specification. Accordingly, this aspect of the rejection is improper and should be withdrawn.

(b) With respect to the assertion that for claim 19 “the relative configuration of the components cannot be determined” – the assertion is neither supported by fact nor reasoning. Claim 19 explicitly recites a carbon nanotube having an ECL label and an enzyme co-factor attached to the outer surface thereof.

There was no basis to assert that the recited “ECL label is attached inside the nanotube” (Final Office Action, at page 3). The specification teaches modifying the carbon nanotube with functional groups to allow for the attachment of the components.

Second, Applicants maintain that the configuration comprising an ECL label attached inside the nanotube is not covered by the claim language. The specification teaches modifying the carbon nanotube with functional groups to allow for the attachment of the components and, more specifically, teaches attachment of the component to the outer surface of the nanotube. *See, e.g.*, Figures 7 and 8.

Although Applicants disagree with the basis for the Examiner’s objection, in order to further prosecution, claims 19, 25 and 26 have been amended to specify that the claimed components are attached to the outer surface of the carbon nanotube. It is believed that all bases for rejection have been obviated by the current amendment.

(c) Claims 28 and 29 have been amended, as suggested by the Examiner. The rejection is rendered moot by the amendment.

(e) With respect to claims 37 and 38, the Examiner asserts that the claims are allegedly “incomplete for omitting essential steps, such omission amounting to a gap between the steps.” More specifically, the Examiner asserts that the “omitted steps are: (i) any requirement for a reaction between the ‘analyte’ and a component of the ‘composition’ which would trigger an ECL response and (ii) a step which correlates the ECL detection with the ‘presence or amount of analyte in the sample’” (Final Office Action, at page 3).

One of ordinary skill in the art would readily understand the meaning and scope of claims 37 and 38 when properly construed in view of the specification. The Examiner is again reminded that breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d

689, 169 USPQ 597 (CCPA 1971). (MPEP Section 2173.04, emphasis added). Nevertheless, to further prosecution of the application, Applicants have amended claim 37 to specify that “the presence of an analyte of interest causes oxidation or reduction of said enzyme co-factor”. The connection between the oxidation state of these NAD or NADP type cofactors and the ECL generated by the composition of the claims is clearly described in the specification.

Accordingly, Applicants submit that claims 37 and 38 are sufficiently clear and definite to one of ordinary skill in the art in view of the specification. Therefore, this aspect of the rejection should be withdrawn.

V. Obviousness-Type Double Patenting

Claims 19-38 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 of US Patent No. 5,866,434 (herein “’434 patent”). This rejection was reiterated in the Advisory Action. In support of the rejection, the Examiner relies on the disclosure in the specification of the cited reference, *e.g.*, “as described at col. 49, line 63 – col. 50, line 10 of US 5,866,434” (Final Office Action, page 5).

Determination for an obviousness type double patenting rejection must be based on the comparison of the currently pending claims to the previously issued claims. *In re Berg*, 46 U.S.P.Q.2d 1226 (Fed.Cir. 1998). Thus, Applicants submit that the ‘434 patent specification’s teachings cannot be used as prior art in an obviousness type double patenting analysis with the ‘434 patent claims since only the disclosure of the invention claimed in the ‘434 patent claims may be examined. *In re Vogel*, 422 F.2d 438, 441-42, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970).

The Examiner has made no allegation that the currently pending claims are by themselves obvious over claims of the ‘434 patent. Applicants respectfully assert that the Examiner did not meet her burden and, therefore, an obviousness type double patenting rejection is not warranted.

Further, currently amended claim 19 is explicitly directed to enzyme co-factors selected from a group consisting of NADH, NADPH, NAD⁺, NADP⁺ or a derivative thereof. Specific enzyme co-factors of currently amended claim 19 are not obvious over claims of '434 patent, cited by the Examiner.

Nonetheless, although Applicants disagree with the basis of the Examiner's rejection, in order to expedite prosecution, Applicants offer to file a terminal disclaimer, so that the term of the present patent will not extend beyond the term of the 5,886,434 patent.

VII. Informalities in Claims 19, 26 and 37 As Noted in the Advisory Action

Applicants would like to thank the Examiner for pointing out the informalities in claims 19, 26 and 37 as recited in the Amendment After Final Rejection. All of such informalities have been corrected.

VII. Consideration of Information Disclosure Statement

In the Advisory Action the Examiner explained that the IDS filed on April 25, 2005 was not considered. Applicants respectfully request that this IDS be considered now. A duplicate Form 1449 has been provided for the Examiner to initial.

CONCLUSION

In view of the comments and remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

No additional fees are believed necessary for entry of this Amendment. However, the Commissioner is hereby authorized to charge any additional fee to Deposit Account No. 50-0540.

Respectfully submitted,
KRAMER LEVIN NAFTALIS & FRANKEL LLP
Attorneys for Applicants

By: 

Aaron S. Haleva
Reg. No. 44,733
Barry Evans
Reg. No. 22,802
Tel. (212) 715-7773
Fax (212) 715 9397